BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

As rescanning documents *will not* correct images, please do not report the images to the Image Problem Mailbox.

(19) Europäisches Patentamt
European Patent Office
Office européen des brevets

(11) EP 0 783 899 A2

(12) EUROPEAN PATENT APPLICATION

(43) Date of publication:
16.07.1997 Bulletin 1997/29

(51) Int. Cl.[6]: **A61M 39/04**, A61B 5/14

(21) Application number: **97200655.5**

(22) Date of filing: **04.04.1990**

(84) Designated Contracting States:
BE DE FR GB NL SE

(30) Priority: **10.04.1989 US 335927**

(62) Document number(s) of the earlier application(s) in accordance with Art. 76 EPC:
90906600.3 / 0 592 391

(71) Applicant: **BAXTER INTERNATIONAL INC.**
Deerfield, IL 60015-4633 (US)

(72) Inventors:
- **Jepson, Steven C.**
  Palatine, Illinois 60067 (US)
- **Noblitt, Brent**
  Irvine, California 92714 (US)
- **Dudar, Thomas E.**
  Palatine, Illinois 60067 (US)
- **Shepherd, David J.**
  Laguna Hills, California 92653 (US)
- **Minallo, Michael**
  Newport Beach, California 92663 (US)
- **Gordon, Mark G.**
  Tustin, California 92680 (US)

(74) Representative: **MacGregor, Gordon et al**
ERIC POTTER CLARKSON
St. Mary's Court
St. Mary's Gate
Nottingham, NG1 1LE (GB)

Remarks:
This application was filed on 05 - 03 - 1997 as a divisional application to the application mentioned under INID code 62.

(54) Blood sampling apparatus

(57) An in-line blood sampling site is provided having a housing (558) with an access port (564) provided with a septum for receiving a blunt cannula (577). The housing has a blood inlet and a blood outlet communicating with the port and axially offset longitudinally of the access port to form a "Z" like configuration. This arrangement facilitates debubbling during filling of the line and ease of blood clearance after sampling.

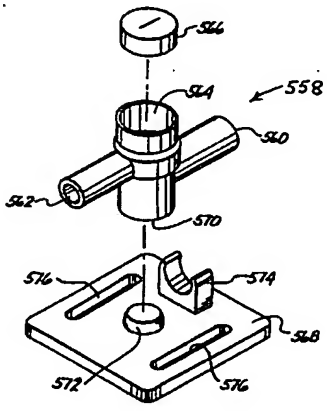


Fig. 22

EP 0 783 899 A2

Description

The invention pertains to blood sampling apparatus.

Such apparatus is disclosed in US-A-4673386 and comprises blood sampling apparatus comprising a fluid line with connecting means for connection to a patient, a reservoir assembly connected in-line and actuable to draw blood along the line between the reservoir assembling and the connecting means and into the reservoir assembly, and a blood sampling site having a housing provided with an inlet and outlet and defining a blood channel therebetween, the sampling site being connected in-line between the reservoir assembly and the connecting means and having a port for removal of a blood sample from the channel.

The precharacterising part of Claim 1 is based on this disclosure and the characterising part of that claim defines the distinguishing features of the invention.

In the prior art apparatus, a stopcock or three-way valve is provided for blood withdrawal. The present invention provides a sampling site instead, the sampling site having a septum for receiving a blunt cannula. The septum is received in an access port which communicates with a blood channel. An inlet to the channel and an outlet from the channel form a "Z" like arrangement with the access port, being axially offset longitudinally of the access port.

This arrangement facilitates debubbling during initial filling of the line and ease of blood clearance after sampling.

One injection site usable with a piercing cannula is disclosed in US Patent No 4,412,573 to Zdeb entitled "Injection Site".

The pointed cannula can be forced through the septum into fluid flow communication with the flow path in the housing. Known injection sites usable with a piercing cannula can be physically damaged by repetitive piercing caused by the sharp cannula. This damage, known as coring or laceration, can result in subsequent leakage.

Due to problems associated with infectious agents, personnel using such pointed cannulae do so with great care. Notwithstanding careful and prudent practice, from time to time, accidents do occur and individuals using such pointed cannulae jab themselves.

Injection sites usable with a blunt cannula are also known. For example, U.S. Patent No. 4,197,848 issued to Garrett, et al., entitled "Closed Urinary Irrigation Site" and assigned to the assignee of the present invention discloses one such injection site. That injection site is a relatively low pressure device having a relatively thin, molded, sealing member. The sealing member has an opening therethrough.

A blunt cannulae can be forced through the sealing member placing the cannulae into fluid flow communication with a fluid flow pathway in the injection site.

Injection sites of the type noted above usable with a blunt cannula have the advantage that the blunt cannula will not pierce the skin of a user. On the other hand, it is important that the pre-slit injection site reseal with enough force that fluids do not ooze therefrom and that airborne particulate matter, bacterial or viral matter do not enter therethrough.

Hence, there continues to be a need for a pre-slit injection site which can be used with a variety of solutions and over a range of fluid pressures. Further, there continues to be a need for such a pre-slit injection site which will reliably reseal even after many insertions of the blunt cannula.

Such an injection site should be able to receive a large number of insertions of the cannula without displaying reseal failure. Such an injection site should provide for improved alignment of the cannula on insertion. Improved alignment will result in less chance of damage to the injection site after repeated insertions of the cannula. Preferably, the injection site would also be usable with a pointed cannula. Preferably, a pre-slit injection site usable with a blunt cannula will provide a reasonable level of insertion force such that health care personnel will readily be able to insert the blunt cannula, yet the cannula will not easily fall from or drop out of contact with the septum.

The sealing member in the apparatus of the invention can be a cylindrically shaped rubber member and an annular channel may underline the sealing member.

A retaining member can be used to retain the sealing member within the housing. The retaining member can be generally U-shaped. Alternately, the retaining member can be formed as a coiled spring.

The retaining member applies axially directed forces to the sealing member. The retaining member may deflect the sealing member and forms a curved exterior peripheral surface thereon. The curved exterior peripheral surface is an easily wipeable surface. The retaining member may deflect the sealing member and forms a curved exterior peripheral surface thereon. The curved exterior peripheral surface is an easily wipeable surface.

The retaining member deflects or distorts the upper and lower peripheral edges slightly as a result of applying axial forces thereto. When the blunt cannula is inserted into the slit in the sealing member, an annular interior peripheral region of the sealing member deforms further and fills, at least in part, the annular channel.

Deformation of this annular peripheral region results in an insertion force in a range of 2.0 pounds (.7564 kilograms) to 5.0 pounds (1.891 kilograms). Preferably, the insertion force will have a value of the order of 2.0 pounds (.7564 kilograms).

The resealable opening in the sealing member can extend entirely through that member. Alternately, the resealable opening can extend only partway therethrough. In this embodiment, the end of the blunt cannula will be used to tear through the remainder of the sealing member.

The sealing member can be formed in two parts. An

exterior cylindrical portion can be slit completely. An interior cylindrical unslit portion can be provided to seal the site until the blunt cannula is inserted therethrough the first time.

The interior surface of the first end can be formed with the taper in a range on the order of 5 degrees to 20 degrees. Preferably, the interior surface will have a taper on the order of 12 degrees. This tapered surface permits the use of a cylindrically shaped sealing member.

To provide for leak-free insertion, the length of the slit in the sealing member must be less than one-half the circumference of the cannula being inserted therethrough. Hence, the slit length may exceed the diameter of the cannula being inserted. In addition, the slit length must be great enough, given the elastic limit of the sealing member, to prevent tearing during insertion.

Numerous other advantages and features of the present invention will become readily apparent from the following detailed description of the invention and the embodiments thereof, from the claims and from the accompanying drawings in which the details for the invention are fully and completely disclosed as a part of this specification.

Brief Description of the Drawings

Figure 1 is a side elevational view, partly in section, of a prior art pre-slit injection site and an associated blunt cannula;

Figure 2A is a view in perspective of a catheter positioned in the hand of a patient with a pre-slit injection site positioned adjacent thereto;

Figure 2B is a perspective view of the catheter of Figure 2A with a pre-slit injection site rotatably affixed thereto;

Figure 3 is an enlarged side elevational view in a section of a pre-slit injection site formed on a body having a luer twist-lock type connector for coupling to a catheter;

Figure 4A is an exploded view of a pre-slit injection sire, a shielded blunt cannula and a syringe prior to being coupled together;

Figure 4B is an enlarged, side elevational view in section of the pre-slit injection site, the shielded blunt cannula and the syringe of Figure 4A coupled together to form a sealed fluid flow system;

Figure 5A is a view in perspective of a pre-slit injection site prior to engaging a blunt cannula carrying a locking member;

Figure 5B is an enlarged side elevational view, partly broken away, illustrating the interrelationship between the pre-slit injection site and the blunt cannula of Figure 5A;

Figure 6 is an enlarged fragmentary side elevational view in section of a coupling member carrying a pre-slit injection site where the slit extends only partway through the septum;

Figure 7 is a step in the method of making a pre-slit injection site;

Figure 8 is another step in the method of making a pre-slit injection site;

Figure 9 is an initial phase of a final step in making a pre-slit injection site;

Figure 10 is an intermediate phase of the final step in a method of making a pre-slit injection site;

Figure 11 is a final phase of the final step in a method of making a pre-slit injection site;

Figure 12 illustrates an initial phase in an alternate step of making a pre-slit injection site;

Figure 13 illustrates a final phase of the alternate step in a method of making an injection site;

Figure 14 illustrates yet another alternate step in a method of making a pre-slit injection site;

Figure 15 is a cross-sectional view of a pre-slit in-line injection site in joined relationship with a blunt cannula shown in side elevational view;

Figure 16 is a perspective view of an alternative blunt cannula device in joined and locked relationship with the pre-slit in-line injection site depicted in Figure 15;

Figure 17 is a perspective view, partially broken away, depicting the combination of a syringe and an alternative blunt cannula device for injecting or removing liquid through a pre-slit in-line injection site, such as depicted in Figure 15;

Figure 18 is a perspective view of a blunt cannula shield or top protector for attachment over the end of the blunt cannula device such as depicted in Figure 17;

Figure 19 is a cross-sectional view of an alternative blunt cannula device particularly suited for attachment to a syringe as shown in Figure 17;

Figure 20 is a perspective view of the blunt cannula device shown in Figure 17 in joined relationship with the pre-slit injection site shown in Figure 15;

Figure 21 is a perspective view of the blood sampling system of the present invention with the pre-slit in-line injection site 492 shown in Fig 15;

Figure 22 is a perspective view of a "Z" shaped housing for the pre-slit injection site;

Figure 23 is a perspective view of the blunt cannula and syringe with a rotating shield;

Figure 24 is a perspective view of a blood transfer unit with a pre-slit injection site.

Detailed Description of the Preferred Embodiments

While this invention is susceptible of embodiment in many different forms, there are shown in the drawing and will be described herein in detail specific embodiments thereof with the understanding that the present disclosure is to be considered as an exemplification of the principles of the invention and is not intended to limit the invention to the specific embodiments illustrated.

A prior art pre-slit injection site 10 and associated blunt cannula 12 are illustrated in Figure 1. The prior art injection site 10 has a cylindrical housing 14 with a fluid flow path 16 therethrough. A first end 18 of the housing

14 is closed with a relatively thin disc-shaped resealable member 20. The member 20 has a resealable opening 22 therein.

The member 20 is a molded septum with an integrally formed skirt 20a. The skirt 20a is oriented generally perpendicular to the portion of the septum with the opening 22.

The cannula 12 includes a body portion 24 which carries at a first end a hollow, cylindrical, blunt piercing member 26. As the cannula 12 is moved in a direction 28 toward the first end 18 of the injection site 10, the member 26 slidably engages the opening 22. The sealing member 20 is then deformed adjacent the opening 22 and the number 26 extends into the flow path 16. A fluid flow path through the cannula 12 will then be in fluid flow communication with the flow path 16 via the hollow piercing member 26.

In contradistinction to the prior art pre-slit injection site 10 of Figure 1, Figures 2A and 2B illustrate a pre-slit injection site 34 being coupled to a peripheral venous catheter 36. The catheter 36 is shown in fluid flow communication with a vein in a hand H of a patient. The catheter 36 carries at a proximal end 38 a liner-type female twist lock connector 41.

The pre-slit injection site 34 is formed with a cylindrical housing 40 having a first end 42 and a second end 44.

Carried by the housing 40, adjacent the second end 44 is a hollow cylindrical fluid flow member 46. The member 46 slidably engages a receiving member in the housing 38 of the catheter 36, thereby providing a sterile fluid flow coupling as is well known and conventional.

A plurality of internal male liner-type threads 48 is carried by the housing 40 adjacent the second end 44. The threads 48 will engage the flange member 41 when the injection site 34 is rotated in a direction 50. When so coupled together, the catheter 36 and the injection site 40 provide a sealed coupling through which fluids may be injected into the vein of the hand H.

Figure 3 illustrates, in section, further details of the injection site 34. A resealable septum 52 is carried by the first end 42 of the housing 40. The septum 52 includes first and second spaced apart surfaces 54 and 56 respectively. The surface 54 has been forced into a dome-like shape by annular, U-shaped, swaged end members 58 carried by the first end 42. The dome-like shape of the surface 54 can extend beyond a surface 42a of the first end 42. This facilitates cleaning the surface 54.

The septum 52 has a generally cylindrical shape. The septum 52 can be formed of a latex or synthetic rubber material. Alternately, the septum can be formed of a thermoplastic elastomer. The material used for the septum 52 should be non-toxic and sterilizable such as by means of radiation, steam or Ethylene Oxide.

Because the septum 52 is generally cylindrical in shape, it can be die-cut from a sheet, cut from an extruded rod or molded. The septum 52 can have an exemplary diameter on the order of .30 inches (0.762 centimeters). The height of the septum 52 can be, for example, on the order of .125 inches (.3175 centimeters).

The first end 42 is also formed with a tapered interior surface 60 which terminates in an annular channel 62. The tapered interior surface 60 has a taper In a range of 5 degrees to 20 degrees. Preferably, the taper will be on the order of 12 degrees. With the indicated size of the above noted exemplary septum 52 and a 12 degree taper, diametric resealing compression of the septum 52 adjacent the channel 62 is on the order of 10%.

The channel 62 is bounded in part by a septum supporting ridge 62a. The channel 62 can typically have a depth in a range of .050-.070 inches (.127 - .1778 centimeters).

A peripheral surface 64 of the septum 52 slidably engages the tapered interior surface 60 as the septum 52 slides into the first end 42. The annular channel 62 which underlies the interior peripheral surface 56 of the septum 52 is provided to permit the septum 52 to deform when a blunt cannula is inserted through an opening 66 therein.

The housing 40 is also formed with a fluid flow path 68 such that fluids injected via a blunt cannula inserted through the resealable opening 66 can flow into the catheter 36 for delivery to hand H of the patient.

The swaged end members 58 apply axial forces to the septum 52 thereby creating the domed exterior peripheral surface 54. The axial forces applied by the end members 58 slightly deform the regions 52a and 52b. In contradistinction, the tapered internal surface 60 applies radially directed forces to the septum 52, thereby forcing the opening 66 into a resealed condition.

In an alternate embodiment, the surface 52 could be formed as a flat, as opposed to a domed, surface.

Once the injection site 34 is lockingly engaged with the catheter 36, a sealed system is formed through which fluids can be infused into the catheter 36. The resealable septum 52 closes the fluid flow path 68.

Figures 4A and 4B illustrate in combination the injection site 34, a blunt shielded cannula 80 and a syringe of a conventional type 82. The syringe 82, as is well known, can be formed with a cylindrical hollow end 84 which carries a male luer-type twist lock thread 86. A hollow centrally located cylindrical fluid flow member 88 is in fluid flow communication with an interior region 90 of the syringe 82.

The shielded blunt cannula 80 carries at a first end 92 a female luer twist-lock flange 94. The flange 94 will slidably engage the threads 86 of the end 84. Hence, the shielded blunt cannula 80 can be locked to the syringe 82 forming a closed fluid flow pathway. The shielded cannula 80 could alternately be formed fixedly attached to the syringe 82.

The shielded blunt cannula 80 carries a cylindrical hollow protective shield 96 which surrounds a centrally located hollow, elongated cylindrical blunt piercing member 98. The cylindrical blunt piercing member 98

has a total length on the order of three times the thickness of the septum 52 in order to ensure complete penetration. The cylindrical blunt piercing member 98 has a diameter on the order of 1/3 the diameter of the septum 52. The shield 96 is desirable and useful for maintaining the piercing member 98 in an aseptic condition by preventing touch contamination prior to the shielded cannula 80 engaging the pre-slit septum 52. Also, the shield helps to align the piercing member with the pre-slit septum.

The cylindrical blunt piercing member 98 can slidably engage the pre-slit septum 52, best illustrated in Figure 4B, thereby extending through the preformed opening 66 therein. As illustrated in Figure 4B, when the piercing member 98 slidably engages and pierces the septum 52, the region 52a deforms by expanding into and filling, at least in part, the annular channel 62.

The deformation facilitates insertion of the piercing member 98 through the slit 66. Subsequent to the piercing member 98 slidably engaging the injection site 34, the interior region 90 of the syringe 82 is in fluid flow communication with the flow path 68, of the injection site 34 via flow paths 88a and 98a respectively of the syringe and the blunt piercing member 98.

In this engagement condition, the septum 52 seals completely around the piercing member 98. Hence, exterior gases, liquids or airborne matter will be excluded from the channel 68.

Subsequent to infusing fluid from the syringe 82 into the fluid flow pathway 68, hence into the catheter 36 and the hand H of the patient, the syringe 82 with lockingly engaged shielded cannula 80 can be slidably withdrawn from the injection site 34. Subsequent to this withdrawal, the septum 52 reseals the opening 66 therein.

The opening 66 will repeatedly reseal, when the piercing member 98 is removed, provided that the pressure (in the septum 52 of the opening 66) created by interaction of the septum material properties and compression supplied by the housing exceeds the pressure challenge of the fluid contained within. Blunt cannula do not haphazardly core, lacerate, or otherwise damage the sealing interface 66 as conventional needles do, thereby allowing repeatable resealability. However, septum material properties, thickness, and compression allow resealability for a finite number of conventional needle insertions. The combination injection site 34 and catheter 36 then return to its pre-infusion, sealed condition.

Figures 5A and 5B illustrate the pre-slit injection site 34 used in combination with a blunt cannula 80a. The cannula 80a includes a hollow body portion 92a with a liner flange 94a, a piercing member 98a, and manually operable elongated locking members 100a and 100b. Alternately, a tubing member could be affixed to the hollow body portion 92.

Curved end regions 100c of the members 100a and 100b slidably engage the second end 44 of the housing 40 when the piercing member 98a of the blunt cannula 80a has been forced through the pre-formed opening 66, best illustrated in Figure 5B. The embodiment illustrated in Figures 5A and 5B has the advantage that the infusion cannula 80a cannot accidentally disengage from the pre-slit septum 34 during the fluid infusion process. It will be understood that while spring-like deflecting members 100a and 100b are illustrated in Figures 5A and 5B that other forms of locking members are within the spirit and scope of the present invention.

As an alternate to forming the slit 66d completely through the septum 52d, as illustrated din Figure 6, a slit 66e can be formed only partly through the septum 52e. Such a structure has the further advantage that, until used for the first time, the septum 52e is completely sealed.

The septum 52e can be formed in two parts. One part can have a slit, such as the slit 66e, extending entirely therethrough. A second part can be formed without a slit. These two parts can be located adjacent one another in the first end 42e of the injection site.

The slit 66e may be longer on the top of the septum than the bottom. This feature aids blunt cannula alignment with the slit upon insertion, and aids resealability by minimizing the critical slit sealing interface area.

The slit could have a length with a range on the order of .03 inches (0.762 centimeters) to .150 inches (.381 centimeters). Preferably, a slit length on the order of .07 inches (.1778 centimeters) will be used in combination with a blunt cannula having a diameter on the order of .1 inches (.254 centimeters).

When initially used, the blunt cannula piercing member, such as the member 98, will be forced through the slit 66a. The lower peripheral surface 56e will then be punctured, providing access for the blunt cannula piercing member 98 into the fluid flow pathway 68e.

In a first step (Fig 7), a housing 200 is provided. The housing 200 has an interior tapered surface 202 at a first end 202a thereof. The interior peripheral surface terminates in an annular channel 204. A cylindrical septum 206 can be provided adjacent the end 200a.

In a second step (Fig 8), the septum 206 can be forced into the end 202a of the housing 200 and slightly deformed by the tapered peripheral surface 202 using an axially moving die 210. When positioned by the die 210, the septum 206 is located adjacent an internal annular right 212 which bounds the annular channel 204.

In a third step (Fig 9), a second die 214 can be utilized to swage the end 200a into spiral-shaped, spring-like members 200b (Fig 10) which apply axially directed forces against an exterior peripheral surface 206a of the septum 206. The axially directed forces form the flat surface 206a into a domed exterior peripheral surface 206b as illustrated in Figure 11.

Simultaneously, with swaging the end members 200a so as to lock the septum 206 into the housing 200 and to form the domed exterior peripheral surface 206b, a knife 216 can be utilized to form a slit in the septum 206. Alternatively, the slit may be cut by a separate die

in a separate step. If the septum 206 is formed as an extrusion, the slit can be created during the extrusion process. If the septum 206 is formed by stamping from a rubber sheet, the slit can be cut during the stamping process. If the septum 206 is formed by compression molding, the slit can be cut during the trimming process.

In order to extrude the slit into rod, a flat pin extrusion bushing can be used. A trailing ribbon may be attached to the bushing. The ribbon would prevent curing material across the slit. The ribbon or wire could be placed in the rod core and later stripped out leaving a slit. An inert substance, such as silicone oil, could be coextruded in the center of the rod to prevent curing across the slit and provide lubrication and a visible target for cannula insertion.

Figures 12 and 13 illustrate alternate swaging steps wherein a die 220 moving axially toward the housing 200 swages the end region 200a so as to form an annular U-shaped region 200c and the exterior domed peripheral surface 206c.

The dies 214 or 220 can be formed with various alternate shaped swaging surfaces 224, as illustrated in Figure 14, depending on the precise shape of the end swage which is desired.

Figure 15 shows, in cross-sectional view, a further alternative device 492 which may employ the pre-slit injection site. The pre-slit injection site device 492 depicted in Figure 15 is an in-line device, preferably for adding medication to a fluid stream, removing a sample from a fluid stream, or similar application. The device depicted in Figure 15 has a fluid entry port 494 at one end, a fluid exit port 496 at the other end, and a fluid passageway 498 communicating directly between the entry and exit ports. The inlet and outlet may have such additional features as are useful connecting the injection site device within a fluid flow path. As depicted, the inlet defines a slightly tapered female surface and the outlet defines a similarly female tapered surface which are preferably joined by solvent bonding a similar attachment to plastic tubing of an administration set, extension set or the like. Standard luer fittings or surfaces could also be provided at the inlet or outlet, as desired.

For injecting liquid into the fluid stream or sampling the fluid stream, the device has a side channel 496 which communicates between a pre-slit septum 502 made and assembled in accordance with the present invention, and the fluid passageway 498. The septum 502 is made as described above, and mounted and held in position by a swaged-over wall 504, as previously described, which may include a colored identifier ring around the septum.

A blunt cannula, such as cannula 506, may be inserted through the pre-slit septum for injecting fluid into the liquid stream flowing between the inlet and outlet, or for taking samples of the fluid stream.

The in-line injection site device 492 shown in Figure 15 may be used in combination with a bare blunt cannula, such as that depicted in Figure 15, or may be used in combination with the blunt cannula device 458, depicted in Figure 16, when a locking relationship between the blunt cannula and injection site is desired.

As depicted in Figure 16, the blunt cannula device 458 may be attached in a secure locking relationship to the in-line injection sire 492. As shown there, the in-line injection site has a radially extending shoulder 508 on each side of the housing, for engaging against the retention means 468 on the end of the resilient gripping fingers 460. The in-line injection site also includes a generally tapered surface 510 defined on the exterior surface for spreading the retention means as the blunt cannula is inserted into the injection site. Insertion of the blunt cannula into the injection site results in the retention means being spread by the tapered surface 510 and, as the blunt cannula is inserted farther, the retention means snap into a locking position behind the radial shoulder 508. In this arrangement, the blunt cannula is securely locked onto the injection site and inadvertent withdrawal is thus prevented. To remove the blunt cannula from the in-line injection site, the gripping ends 470 of the resilient fingers are squeezed, causing spreading of the retention means 468 and release from the injection site. The cannula may then be simply removed by withdrawing it from the injection site.

Figure 17 depicts a blunt cannula device 512 embodying the present invention in combination with a syringe 514. The blunt cannula device 512 has a generally cylindrical outer wall 516 which encloses and substantially protects a blunt cannula portion 518. The blunt cannula portion is attached to and extends from an intermediate transverse interior wall 520. The blunt cannula device 512 may be attached to a syringe in various ways. As depicted, however, the syringe 514 has a glass barrel wall which is tightly press fit into one end of the cylindrical outer wall, extending therewithin to the transverse wall 520.

The syringe depicted in Figure 17 is of the type prefilled with a medical liquid such as heparin. Although it does not form a part of the present invention, for purposes of completeness, the syringe depicted in Figure 17 has a pair of resilient pistons 522 spaced apart, with the fluid to be dispensed contained between the pistons. A plunger rod 524 pushes the pistons forward until the forward most piston engages against an entry port 526 which extends in a direction opposite the blunt cannula 518. The forwardmost piston has a frangible portion, which is pierced by the entry port, releasing the liquid contained between the pistons for expulsion through the blunt cannula.

The blunt cannula portion 518 is substantially protected from inadvertent touch contamination by the outer cylindrical wall 516. To permit the blunt cannula to be used, however, with the in-line injection site 492 or a similar device, a pair of opposed, generally U-shaped recesses 528 are provided in the cylindrical wall for receiving the inlet and outlet portions 494,496 of the in-line injection site when the cannula is attached to it. This arrangement is depicted in a perspective view in Figure

56. As shown there, the blunt cannula device 512 may be attached to the in-line injection site by inserting the blunt cannula portion into the pre-slit injection site, with the U-shaped recesses 528 receive the inlet and outlet portions 494,496 of the in-line injection site, thus allowing the bare cannula to be inserted sufficiently far into the pre-slit injection site.

Figure 18 shows a shield or top protector 530 for a blunt cannula device of the type shown in Figure 17. The tip protector 530 has a generally cylindrical outer wall 532 with raised ribs 534 for gripping. The cylindrical wall is sized to slip over the end cylindrical wall 514 of the blunt cannula device 512, and is sufficiently long to extend beyond the U-shaped recesses to completely enclose and protect the blunt cannula 518 during shipping, storing and between uses, if so desired.

Concentrically disposed within the cylindrical wall 532, the tip protector has an axially extending, hollow tube 536 for slidably receiving the blunt cannula 518 therewithin. The shield or tip protector 530 would typically be attached to the blunt cannula device 512 during manufacture, and removed when the syringe and blunt cannula device are used. If so desired, it may be reattached between uses to protect the cannula from any further contamination.

Figure 19 is an alternative embodiment of the blunt cannula device shown in Figure 17, and is depicted without a syringe attached to it. As shown in Figure 19, the blunt cannula device 538 similarly has a cylindrical outer wall 540, a transverse intermediate inner wall 542, a blunt cannula 544 extending axially from the transverse intermediate wall and an entry port 546 extending in the opposite direction from the blunt cannula. The essential difference between this embodiment and the one shown in Figure 17 is the absence of the U-shaped recesses for use with an in-line injection site such as depicted in Figure 20. For ease of attachment to an injection site, the inner surface of the cylindrical wall is preferably tapered at 548.

The in-line injection site device 492 shown in Figure 15 is ideally suited for use in an arterial or venous line blood sampling system such as the one disclosed in US-A-4673386 in the name of Mark Gordon. The following parts of the Gordon patent are incorporated herein by reference as if fully set out herein: Figures 1-6, the specification from Column 1, line 1, to Column 5, line 7, Claims 1-14, and the Abstract.

The in-line injection site device 492 of the present invention would replace the stopcock or three-way valve 49 of the Gordon patent at the blood withdrawal site. Figure 21 shows the blood sampling system of the present invention with the in-line injection site device 492. The fluid entry port 494 and fluid exit port 496 of in-line injection site 492 are preferably joined to the plastic tubing 555 of the administration set by solvent bonding, as opposed to standard luer fittings, to reduce the risk of contamination. Using the pre-slit injection site of the present invention rather than a conventional stopcock at the blood withdrawal site also reduces the risk of contamination.

Referring to Fig. 21, the blood sampling system of the present invention includes a blood reservoir assembly 550, an in-line injection site device 492 (sampling site), a shielded blunt cannula 577 with syringe 582, and a blood transfer unit 552. The reservoir and sampling site are connected via bonded connections to pressure tubing 555 which is in turn bonded to a female luer connector 551 at the inlet side of the reservoir for attachment to a pressure transducer (not shown). The transducer is positioned in-line between the reservoir and a flush valve, downstream from a fluid supply. A male luer connector 553 is bonded to the pressure tubing at the outlet side of the sampling site for attachment to a patient catheter. The entire system is intended to be disposable.

As disclosed and described in the Gordon patent, the reservoir is an in-line syringe type device with housing, cap, plunger and seal which when actuated draws into the internal cavity a blood/saline mixture of approximately 5 cc for the standard adult and approximately 3 cc for the pediatric patient. The fluid is drawn from the patient side as opposed to the transducer side due to the high fluid restriction provided by a micro-bore hole which exists in currently manufactured flush devices. This clears the line between the patient and the sampling site of saline solution or other IV fluid and therefore permits a pure blood sample to be taken from the sampling site. After the sample has been taken, the blood/saline mixture in the reservoir is returned to the patient.

The present invention provides a sampling site housing 558 having an access port 564, an inlet port 560 and an outlet port 562. The inlet and outlet ports 560,562 are axially offset longitudinally of the access port, so as to define generally a "Z" shape as shown in Fig 22. The "Z" housing 558 has the inlet port 560 at the bottom leading to the reservoir and the outlet port 562 at the top leading to the patient to provide for ease of debubbling during initial filling of the patient line with fluid and ease of blood clearing from the reservoir following the sampling process. The top portion 564 of the housing contains a pre-slit septum 566 made and assembled in accordance with the present invention and specifically as shown in Fig.15. An arm or pole mount plate 568 may also be provided for holding the sampling site housing. In a preferred embodiment, the bottom portion 570 of the housing mates with and is bonded to raised pedestal 572. Cradle 574 may also be provided in the mounting plate, if desired, to receive inlet port 560 for alignment purposes. Slots 576 may also be provided for taping or strapping the mount plate to a patient's arm. Other means of aligning the Z-site on the mounting plate include slots in the pedestal mating with tabs or bumps on the interior of the bottom portion of the Z-site housing. The mounting plate can also be molded integral with the Z-site if desired.

A shielded blunt cannula with a sampling syringe such as the one shown in Fig 17 is used with the blood

sampling system of the present invention. The blunt cannula is inserted through the pre-slit septum for withdrawing the blood sample as shown in Fig 15. The blunt cannula and pre-slit injection site replace conventional needles and injection ports or luer lock attachment to the sampling stopcock. The blunt cannula and pre-slit injection sire provide the advantage of reducing or eliminating the risk of needle sticks and blood touch contamination. The blunt cannula and pre-slit injection site also permit repeated cannula insertion and withdrawal without coring which is experienced with conventional needles and injection sites.

Referring to Fig 23, preferably the shielded blunt cannula 577 used with the blood sampling system of the present invention has a rotating shield 578 with U-shaped slots 580 that fit over the inlet and outlet ports of the sampling sire housing as described above with reference to Fig 20. The rotating shield prevents detachment of the blunt cannula from the sampling syringe if the syringe is rotated while attached to the sampling site. In another preferred embodiment, a blunt cannula and shield can be integrally molded into the syringe barrel as shown in Fig 11. This would eliminate the need for a rotating shield since the cannula cannot become disengaged.

In the blood sampling system of the present invention shown in Fig 21, a blood transfer unit 552 is also provided. The blood transfer unit consists of a pre-slit injection site 554 made and assembled in accordance with the present invention and a shroud covered needle 556. Referring to Fig 22, the blood transfer unit is shown with the shroud 584 disengaged from the needle and pre-slit injection sire assembly 585. The needle is bonded to an adapter, a plastic piece with a threaded male connector 590 at one end (the needle end) and a male luer connector at the other end (the pre-slit injection site end). The shroud 584 is preferably a clear plastic housing with a female threaded connector 588 which mates with the male threaded connector 590. The pre-slit injection site has a tubular or cylindrical housing 592 deep enough to receive the blunt cannula 579. The housing has a female luer connector (not shown) that mates with the male luer connector (not shown) on the adapter. In a preferred embodiment, the shroud and pre-slit injection site housing are molded as one piece.

When a blood sample is transferred from the syringe to an evacuated tube, the blunt cannula on the syringe is inserted into the pre-slit injection site 554 and the blood sample flows through the tubular housing 592 of the pre-slit injection site, through the needle 556 into the evacuated tube. The tube is positioned within the shroud to protect the user from needle pricks and blood contamination. Preferably, needle 556 is covered by a rubber sleeve or protector. The sleeve could also be made of any elastomeric material, such as silicone and the like. When the needle is removed from the rubber stopper, the rubber sleeve slides down to cover the needle and prevent blood drops from contacting the user. The rubber sleeve also allows the blood transfer unit to be used for more than one evacuated tube without permitting blood to leak through the needle when the evacuated tube is removed.

Claims

1. Blood sampling apparatus comprising a blood sampling site (492) having a housing (558) provided with an inlet (560), an outlet (562), a blood channel therebetween and an access port (564) communicating with the blood channel, for removal of a blood sample from the channel,
characterised by:
flexible means (566) carried by the housing and sealing the port (564), the flexible means having a resealable opening therein for sealingly receiving a blunt cannula (577) for placing the cannula in fluid communication with the blood channel, the flexible means interacting with the housing to reseal the opening when the cannula is removed, the inlet (560) and the outlet (562) being axially offset from each other longitudinally of the access port (564).

2. Blood sampling apparatus according to Claim 1, comprising a fluid line (555) with connecting means (553) for connection to a patient, a reservoir assembly (550) connected in-line and actuable to draw blood along the line between the connecting means and the reservoir assembly, the inlet (560) and outlet (562) of the sampling site (492) being connected in-line between the connecting means (553) and the reservoir assembly (550).

3. Blood sampling apparatus according to Claim 1 or 2, including a blunt-ended cannula insertable through said opening and having an elongated member (518,544) with a fluid flow channel extending generally axially therewithin and through a distal end of said member; said elongated member being generally cylindrical along a substantial portion of its length and terminating in a generally tapered distal end portion having a blunt end edge.

4. Blood sampling apparatus according to Claim 3, including a substantially cylindrical sheath (516,540) surrounding said elongated member (518,544) and being at least coextensive with and spaced apart from said elongated member to protect said member from inadvertent touch contamination.

5. Blood sampling apparatus according to Claim 4 further including means defining at least two slots (528) opposite one another at the distal end of said sheath (516).

6. Blood sampling apparatus according to Claim 4 wherein said sheath (578) freely rotates around

said elongated member (518).

7. Blood sampling apparatus according to Claim 4 wherein the interior surface of said sheath (540) is outwardly tapered (548).

8. Blood sampling apparatus according to Claim 4 further comprising a generally cylindrical wall (579) extending in the opposite direction from said sheath (578) for receiving the end of a syringe (582) or the like.

9. Blood sampling apparatus according to Claim 4 including an adapter for transferring fluid from the blunt-ended cannula (577), to an evacuated tube, the adapter comprising an injection site (554) having a cylindrical housing (592) and flexible means carried by said housing for sealing one end of said housing, said flexible means having a resealable opening therein and a curved exterior peripheral surface such that the blunt cannula (577) can be sealingly inserted through said opening and placed in fluid flow communication with a needle (556) attached to the other end of said housing, and such that the blunt cannula can be removed therefrom with said flexible means interacting with said housing so as to reseal said resealable opening; a shroud (584) covering said needle and into which an evacuated tube can be inserted when transferring fluid from the syringe to the tube.

10. Blood sampling apparatus according to Claim 9, including an elastomeric sleeve covering said needle (556).

11. A method of sampling blood from a sampling site (492) in a blood line (555) of blood sampling apparatus according to Claim 1 or 2, the method comprising removing a blood sample from the channel through the port (564) of the sampling site by sealingly inserting a blunt cannula (557) through said opening in fluid flow communication with the blood channel and removing blood through the cannula, and removing the cannula, the flexible means (566) interacting with the housing, on removal of the cannula, to reseal the opening.

FIG. 1
PRIOR ART

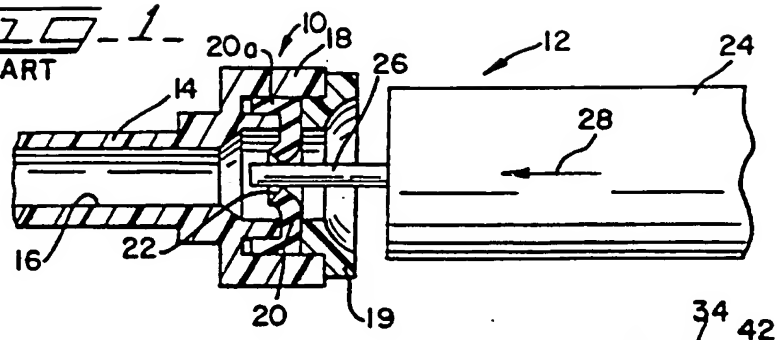


FIG. 2A

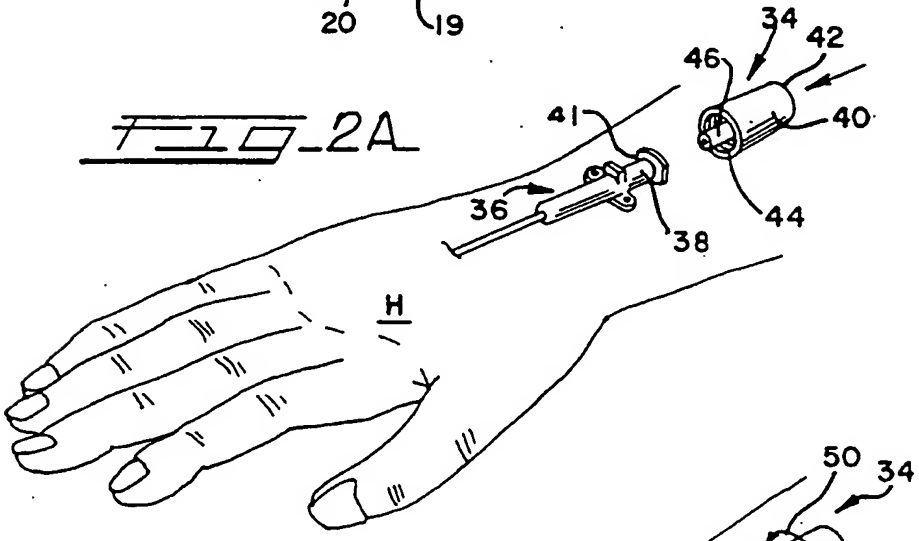


FIG. 2B

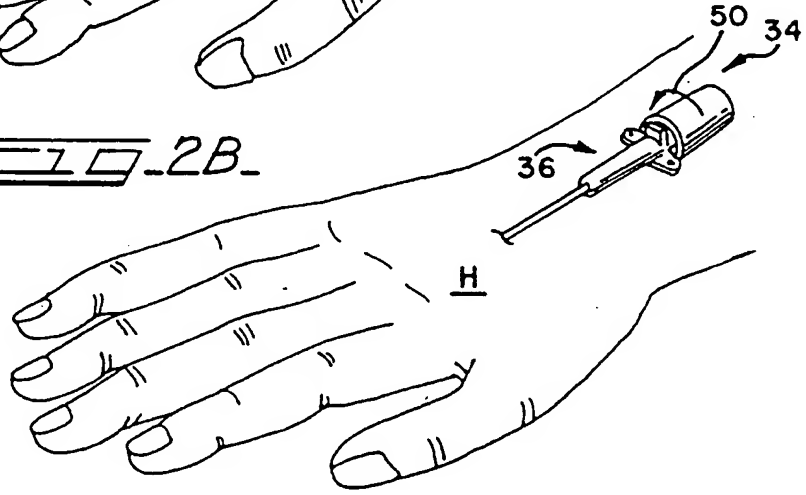


FIG. 3

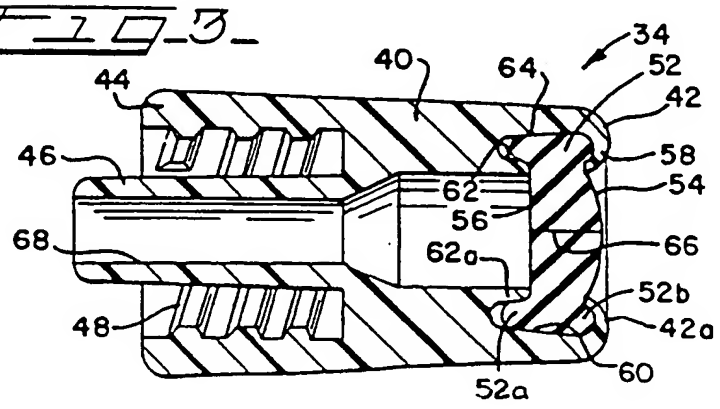


FIG-4A

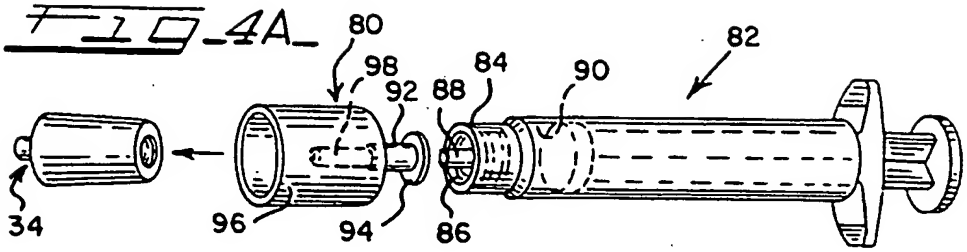


FIG-4B

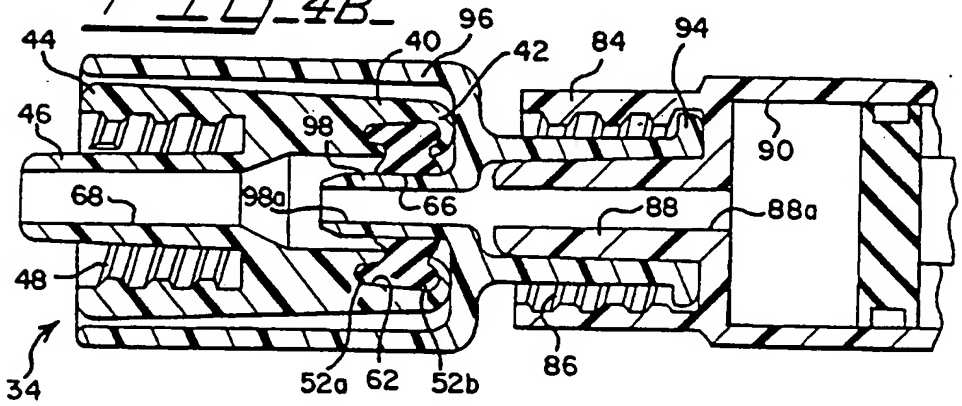


FIG-5A

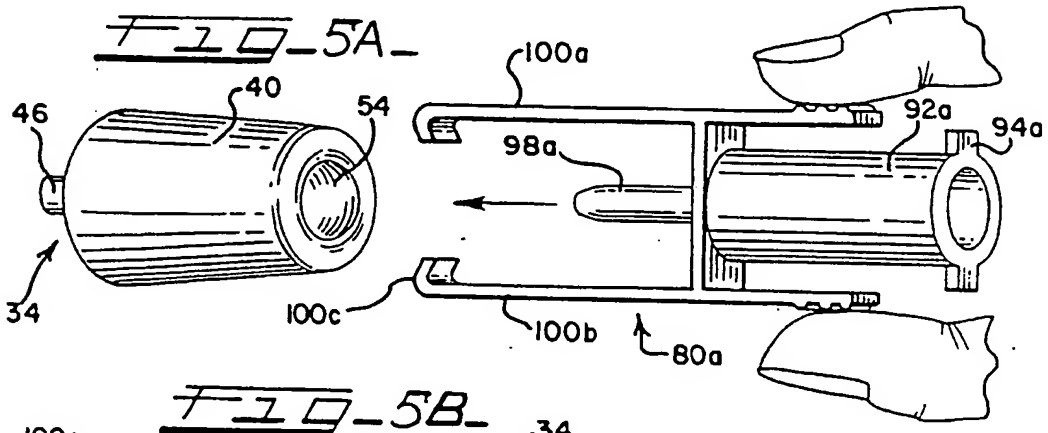


FIG-5B

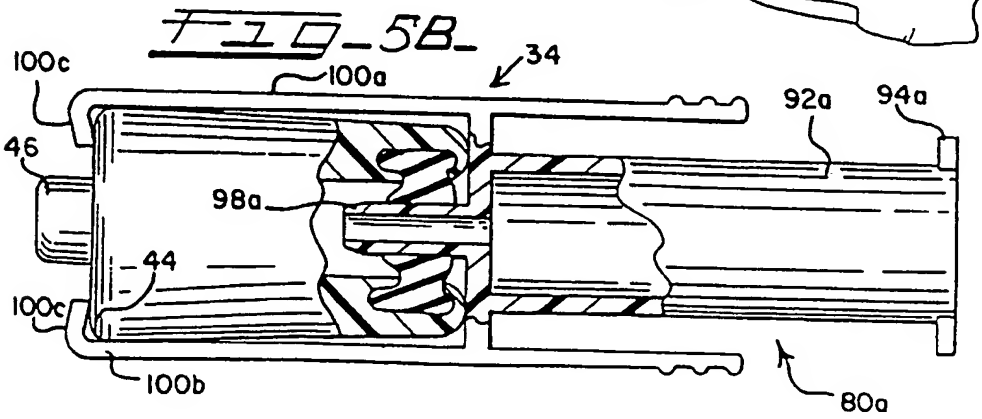


FIG. 7

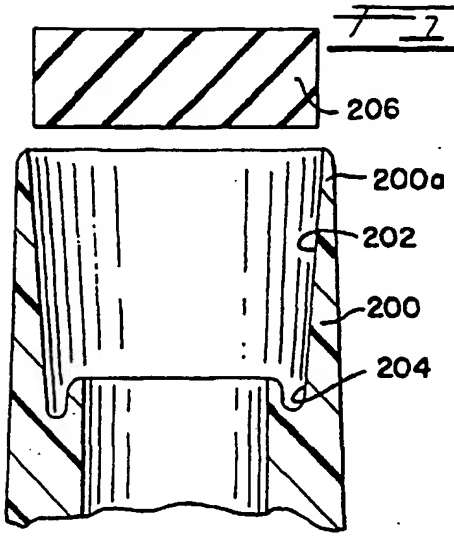


FIG. 8

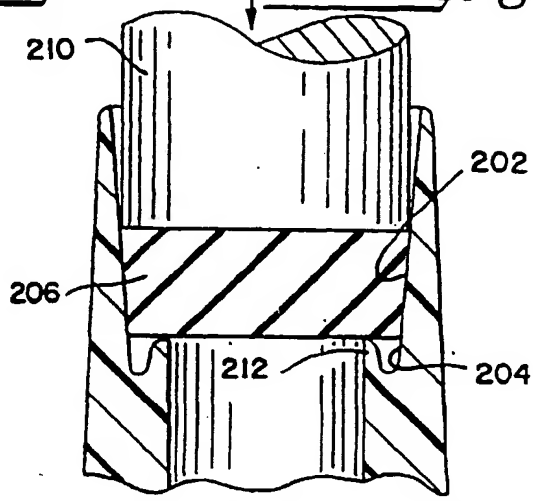


FIG. 9

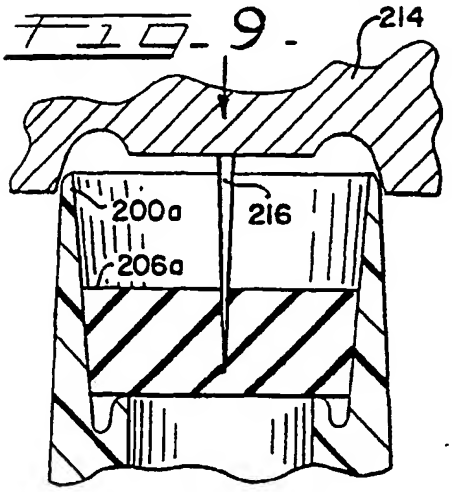


FIG. 10

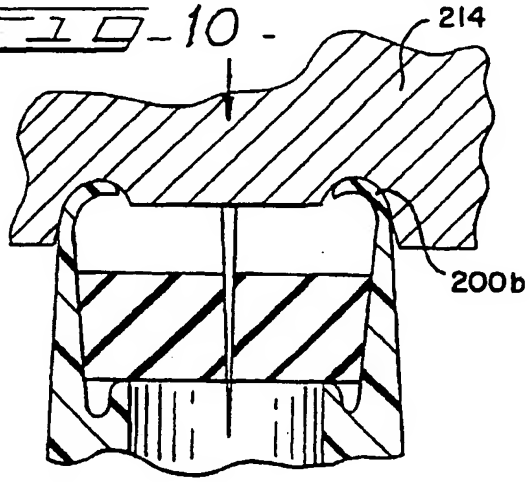


FIG. 11

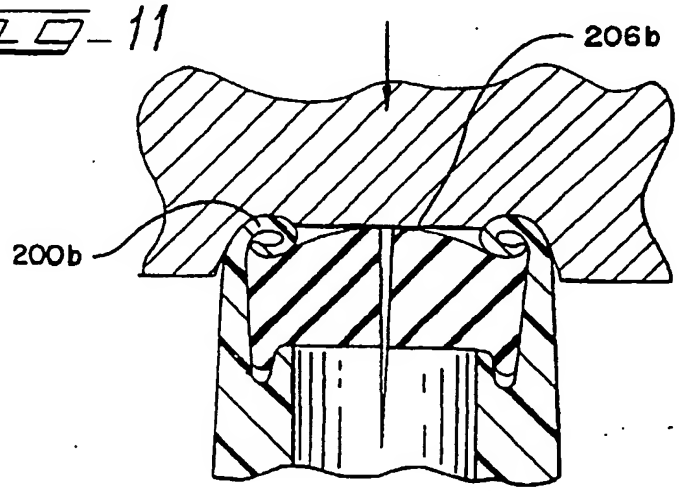


FIG. 12

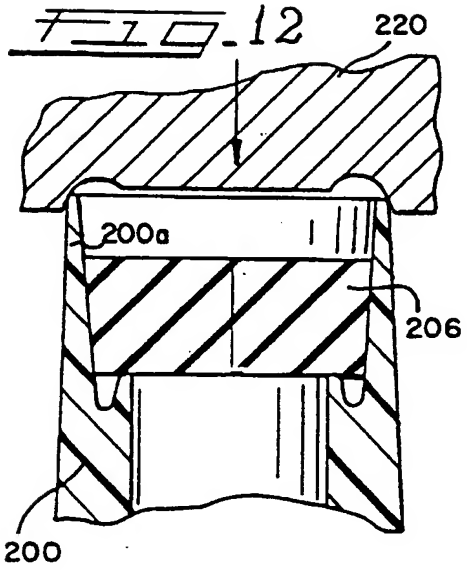


FIG. 13

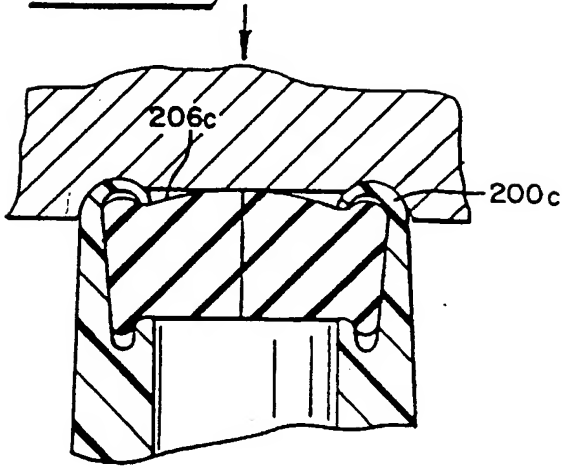
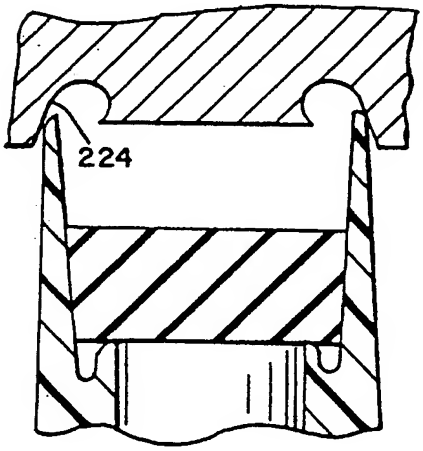


FIG. 14



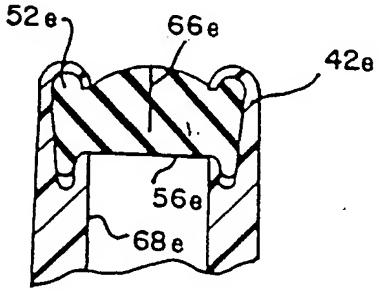


FIG. 6

FIG .15

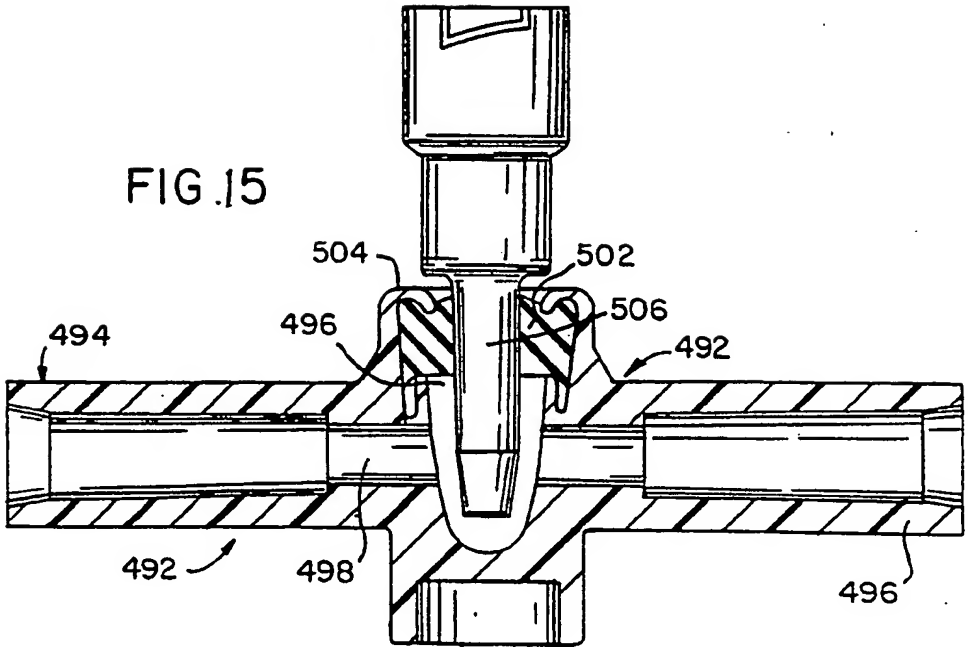


FIG. 16

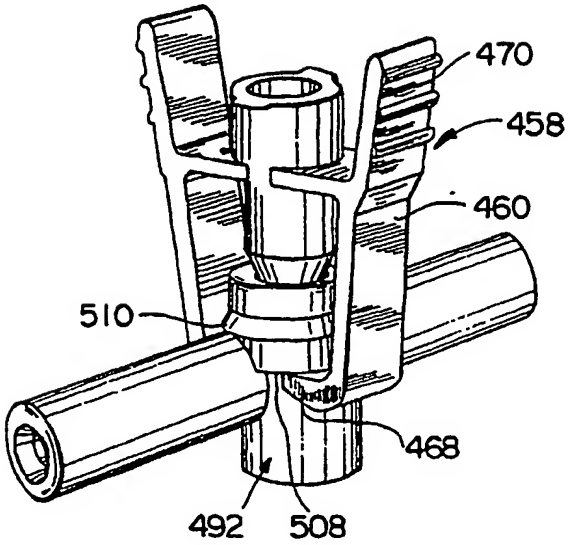
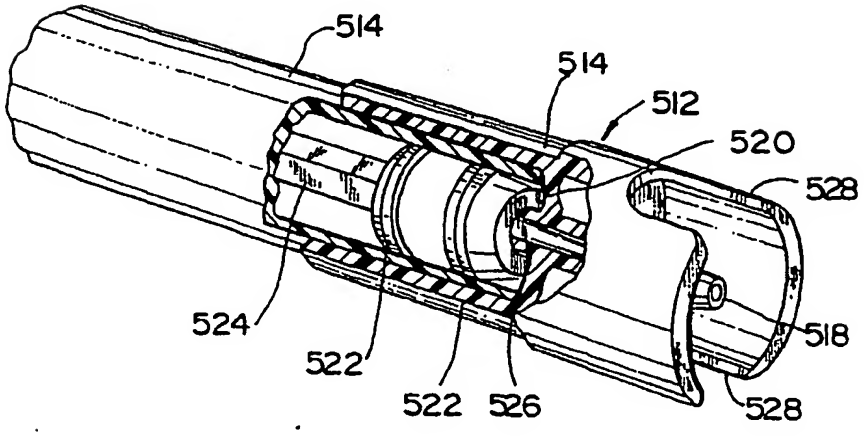

470
458
460
510
468
492
508

FIG. 17


514
514
512
520
528
524
522
522
526
518
528

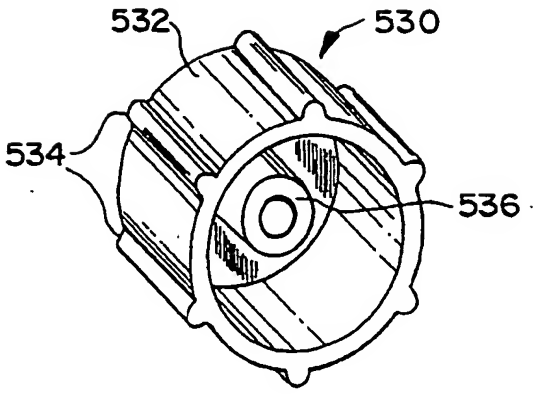


FIG. 18

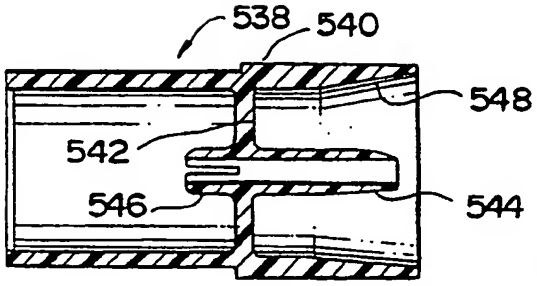


FIG. 19

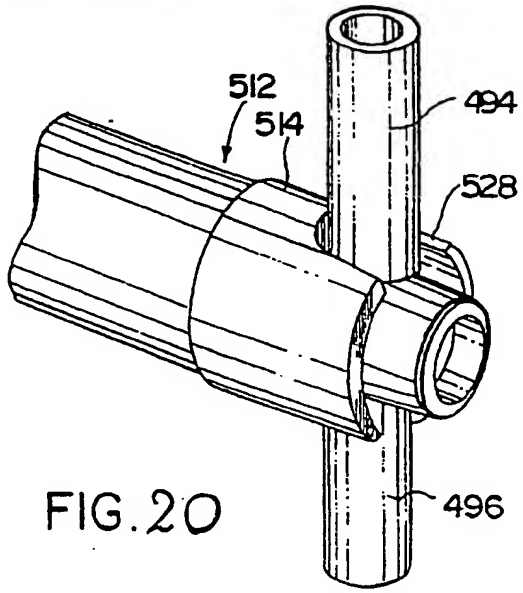
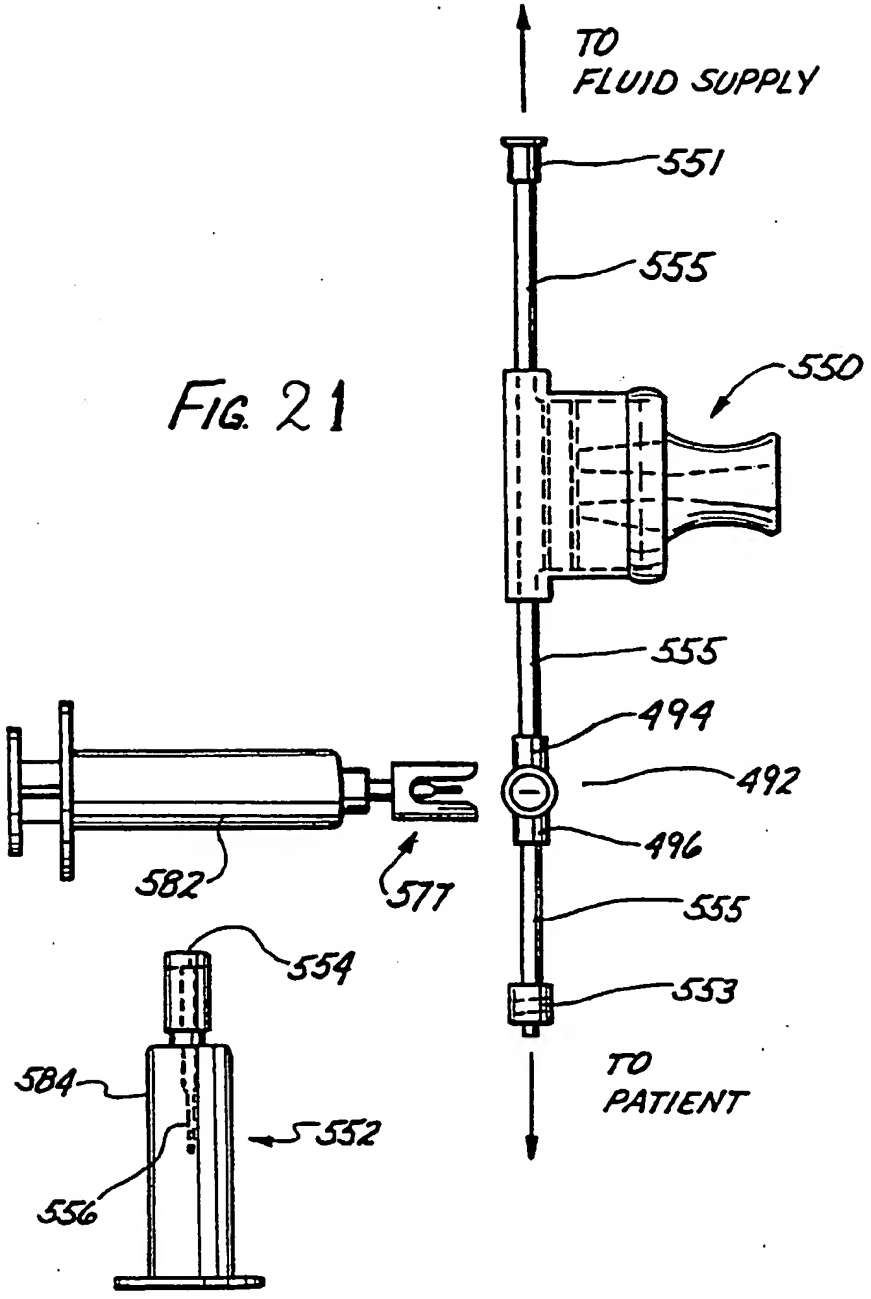


FIG. 20

FIG. 21


TO
FLUID SUPPLY
551
555
550
555
494
492
496
555
553
TO
PATIENT
582
577
554
584
552
556

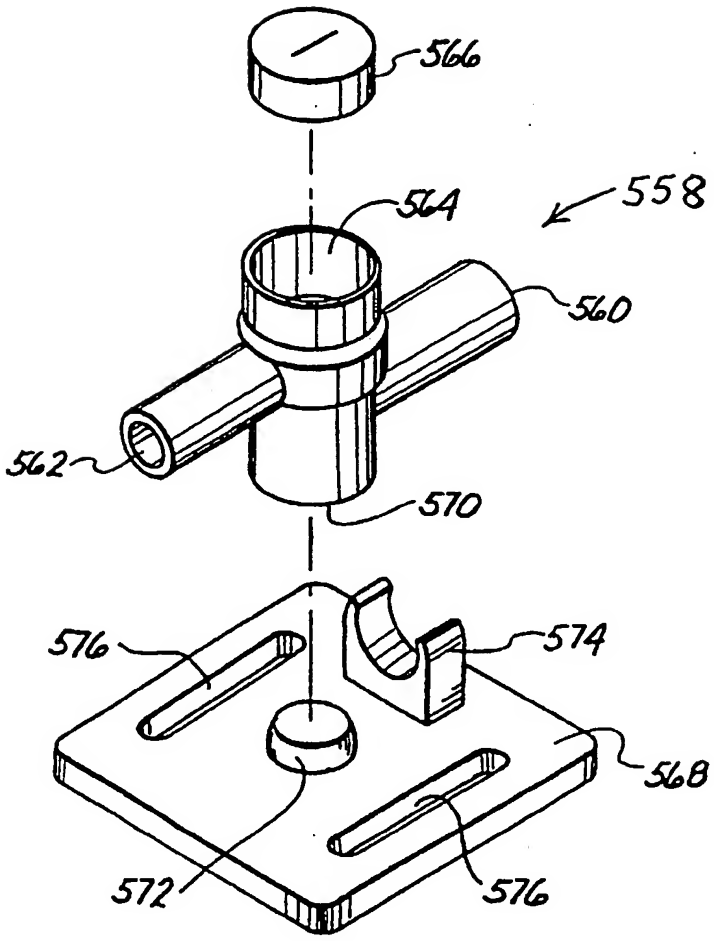


FIG. 22

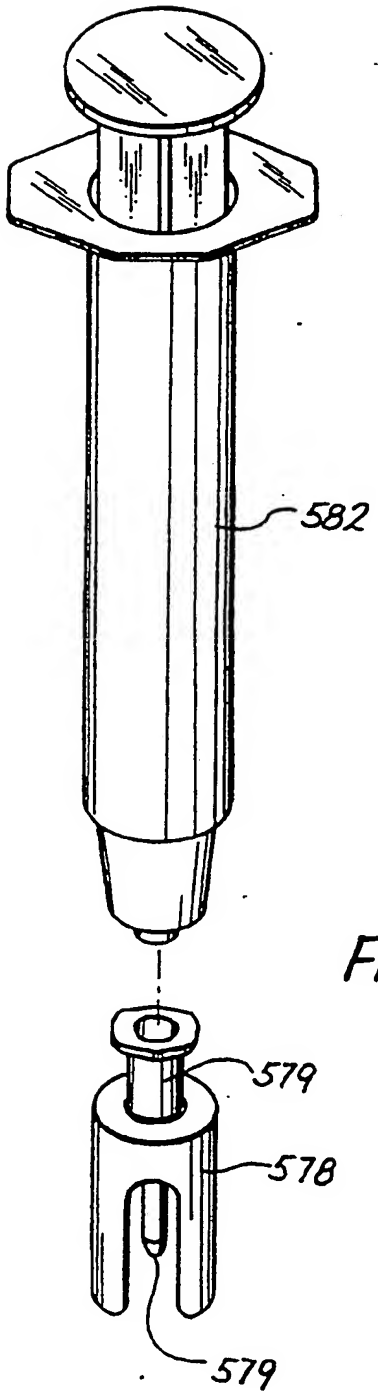


FIG. 23

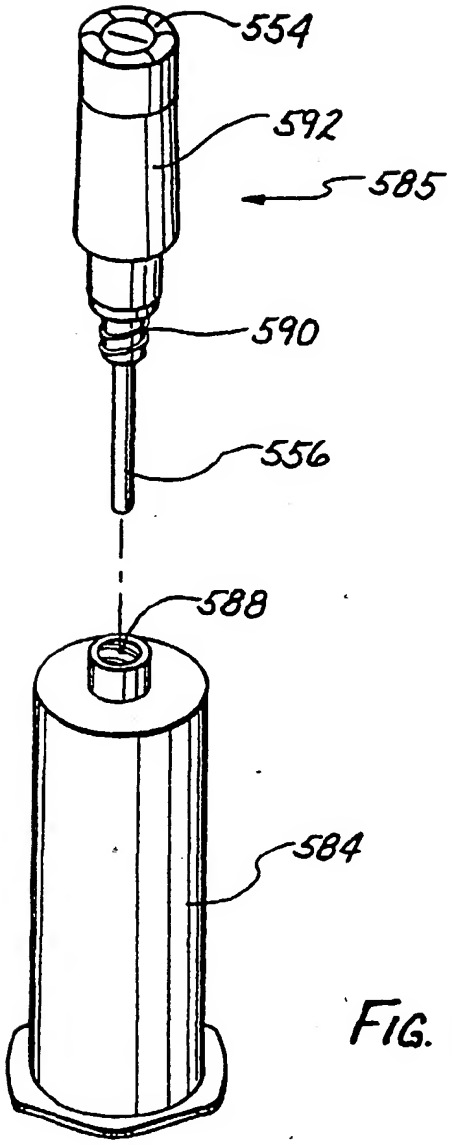


FIG. 24